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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,729	11/13/2001	Moscs Rodriguez	1199-1-005CIP2	4304
23565	7590	10/30/2007	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			KOLKER, DANIEL E	
		ART UNIT	PAPER NUMBER	
		1649		
		MAIL DATE	DELIVERY MODE	
		10/30/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/010,729	RODRIGUEZ ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Daniel Kolker	1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 August 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 42,43,73 and 91-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 73 and 91-93 is/are allowed.
- 6) Claim(s) 42-43 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

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#### **DETAILED ACTION**

1. The remarks and amendments filed 24 August 2007 have been entered. Claims 42 – 43, 73, and 91 – 93 are pending and under examination.

#### ***Withdrawn Rejections and Objections***

2. The rejection of claims 42 – 43 and 91 – 93 under 35 USC 112, first paragraph, is withdrawn in light of the amendments. It is now clear that the heavy chains must comprise the full-length sequences, rather than a fragment.

#### ***Maintained Rejections***

##### ***Priority***

3. The effective filing date of all pending claims is 28 May 1999 for the reasons previously made of record. Applicant did not traverse the examiner's determination of priority.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42 – 43 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies comprising a heavy chain variable sequence comprising the heavy chain variable region of SEQ ID NO:7 and a light chain variable sequence comprising the light chain variable region of SEQ ID NO:9, does not reasonably provide enablement for monoclonal antibody sHlgM22 (LYM 22). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection stands for the reasons made of record. The issues have been fully developed, particularly most recently at pp. 3 – 5 of the office action mailed 13 February 2007. For the sake of brevity, the examiner's arguments are summarized here rather than reiterated in full. The claims encompass monoclonal antibody (mAb) sHlgM22, also known as LYM 22. The art of record (for example Alberts 1994 and Kuby 1997, both cited in office action mailed 13 February 2007) indicate that monoclonal antibodies are large complex molecules and that their

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structures are unpredictable. Even when a small antigen is used many different monoclonal antibodies with unique structures would be expected to be produced. In general, a monoclonal antibody cannot be made without the hybridoma that secretes it or the amino acid sequence of the entire molecule. While it is within the skill of the artisan to make monoclonal antibodies that bind to a given epitope, reproducing a single monoclonal antibody from scratch would be very difficult and unpredictable. In the instant situation, the monoclonal antibodies that are recited in claims 42 – 43 were isolated from a human patient (see Warrington 2001 and Ceric 2000, both of record). Because each human is genetically unique, it is highly unlikely that LYM 22 antibody exists in any humans other than the one who provided the antibody in the first place. The skilled artisan could not obtain the antibody from just any human patient, access to the actual person who makes the antibody.

Applicant argues, on pp. 6 – 7 of the remarks that it is within the skill of the artisan to make many of the fragments and monomers recited in claim 42. The examiner agrees, but notes that both claims 42 and 43 specifically recite LYM 22 antibody, which cannot be made in the absence of undue experimentation. Applicant states, on p. 7 of the remarks, “that the availability of the hybridoma would be helpful or more efficient for the artisan”, and states that confirmation of deposit of same will be provided later. However no such confirmation is currently of record, so the rejection stands.

### ***Conclusion***

5. Claims 42 – 43 are rejected; claims 73 and 91 – 93 are allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Daniel E. Kolker, Ph.D.

October 4, 2007



ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER